SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING JUNE 14, 2001

The Quality Systems Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on June 14, 2001, at 1:00 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Dr. Fred Siegelman of the U.S. Environmental Protection Agency (EPA). A list of action items is given in Attachment A. A list of participants is given in Attachment B. The purpose of the meeting was to discuss the status of the asbestos subcommittee, progress on International Organization for Standardization (ISO) 17025 integration, activities of the microbiology subcommittee, results from the Seventh NELAC Annual Meeting (NELAC 7), plans for the Seventh NELAC Interim Meeting (NELAC 7i), and unfinished business after NELAC 7.

INTRODUCTION

Dr. Siegelman called the meeting to order and reviewed the agenda for the meeting.

TOPICS OF DISCUSSION

Asbestos Subcommittee

Dr. George Kulasingam discussed the status of the asbestos subcommittee's efforts. Three types of testing will eventually be addressed by the subcommittee:

- 1. Fibers in drinking water
- 2. Bulk analysis of hazardous and solid waste
- 3. Fibers in air

Fibers in drinking water, using a transmission electron microscopy (TEM) method, have been addressed. Bulk analysis in waste is under discussion now and the subcommittee hopes to complete development of all of these before NELAC 7i in December 2001.

ISO 17025

Dr. Siegelman stated that the American Society for Testing and Materials (ASTM) now has ISO 17025 available and that this may provide more flexibility in the committee's use of the text. Dr. Siegelman has been told that EPA's lawyers are currently exploring the possibilities of working with ASTM on this. For the draft incorporating the ISO 17025 which this committee had previously prepared, a contractor to Mr. David Friedman has been asked to check it for accuracy and completeness. They will also be adding ISO 17025 references or citations to specific sections of the NELAC Standard to identify the original source of the language. Changes voted on and approved at NELAC 7 will also be incorporated. When this is completed, the ISO 7025 subcommittee, with assistance from this committee, will continue the process of developing a coherent standard from the draft, with groups of two or three people working on assigned sections. Dr. Carl Kircher has also worked on this integration, as part of the performance-based measurement systems (PBMS) subcommittee, and will join the ISO 17025 subcommittee,

contribute to the effort, and serve as a bridge between the two sub-committees. Dr. Siegelman will provide word processing format guidelines and will eventually combine the sections prepared by the different teams. For NELAC 7i, draft standards must be completed by October 1 and published by November 1, in preparation for the meeting on December 3.

Microbiology Subcommittee

Ms. Marty Casstevens discussed the comments that have been received from the U.S. Geological Survey (USGS) and Ms. June Kani of California on media preparation. Ms. Casstevens plans to discuss the issue further with both commenters. If laboratories prepare their own media, they may need to do additional testing, similar to what commercial producers of media are required to perform. The commercial producers typically follow the requirements in clinical standards for media and provide certificates of testing for each batch. A compromise, with comparison of media prepared in-house with commercially-prepared media, might be appropriate. Manufacturer's expiration dates must be followed for media ingredients.

NELAC7

Dr. Siegelman then discussed the NELAC 7 meeting. The proposed integration of ISO 17025 and the NELAC Quality Systems chapter of the NELAC Standard was well received, and the preference was to have the resulting standard organized the same as ISO 17025. All of the changes that were voted on passed, but cannot be implemented immediately at the state level. For NELAC 7i, the major efforts will likely be PBMS and ISO 17025 integration.

UNFINISHED BUSINESS

Mr. Cliff Glowacki will follow up on the comment received on what the requirements should be to demonstrate if a new or reconditioned instrument is capable of meeting the test method requirements.

The Accrediting Authorities concerns and recommendation on subcontracting laboratory analyses has been resolved, according to Dr. Kulasingam.

The committee also discussed the questions from the State of Washington on electronic versus hard copy records and signatures and whether records must be printed to allow the analyst to initial or sign them by hand. The Accrediting Authority Workgroup also addressed the questions about electronic signatures and the information is their May 15 meeting minutes. Dr. Siegelman will prepare a response to the comment dealing with subject and Dr. Kulasingam will review it.

Dr. Siegelman will follow up on a questions from Mr. Richard Spinner on the acceptability of a one point calibration and how to bracket the sample concentrations if only one point is used.

An electronic mail message from the PBMS subcommittee was received, asking about the direction to take on revising the standard. The PBMS subcommittee efforts will be part of the effort to rewrite the standard, integrating the ISO 17025 text, and not a separate parallel effort. The October version of the standard should incorporate all of these changes.

NEXT MEETING

There being no further business, Dr. Siegelman adjourned the meeting. The next meeting is scheduled for July 12, 2001.

ACTION ITEMS QUALITY SYSTEMS COMMITTEE MEETING JUNE 14, 2001

Item No.	Action	Date to be Completed
1.	Continue revisions to the standard, based on ISO 17025 incorporation and PBMS changes (Committee, PBMS Subcommittee, ISO 17025 Subcommittee)	October 1, 2001
2.	Discuss the requirements for media preparation with commenters (Casstevens)	
3.	Follow up on new and reconditioned instruments demonstrations of acceptability (Glowacki)	
4.	Follow up on electronic records and electronic signatures (Siegelman)	
5.	Follow up on the acceptability of one point calibrations (Siegelman)	

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